

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Assaf Govari et al. **Examiner:** Jonathan Cwern
Serial No.: 10/785,162 **Art Unit:** 3737
Filed: February 23, 2004 **Docket:** BIO5042 (SSMP 23303)
For: Robotically Guided Catheter
Conf. Num.: 8493

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Declaration Under 37 C.F.R. §1.131

Sir:

We, Assaf Govari, Andres Claudio Altmann and Yaron Ephrath hereby declare that:

1. We are the Applicants of U.S. Patent Application No. 10/785,162 (hereinafter "the Application").

2. U.S. Patent Application Publication No. 2004/0254566 to Plicchi et al. (hereinafter "the Plicchi reference") has been identified by the Examiner in an Office Action dated September 28, 2009 as a basis for rejecting under 35 U.S.C. §103(a) claims 1-16, 18-21, 23, 24, 35-37, 39-42, 44 and 45 in the Application. The effective date of the Plicchi reference is January 30, 2004.

3. The acts relied upon to establish completion of invention prior to the January 30, 2004 effective date of the Plicchi reference were carried out in the United States and/or in a WTO member country. Specifically, the invention of the subject matter claimed in claims 1-16,

18-21, 23, 24, 35-37, 39-42, 44 and 45 was completed (i) after the January 1, 1996 effective date of section 531 of Public Law 103-465, the Uruguay Round Agreements Act, under which an applicant can establish a date of completion of invention in a WTO member country other than a NAFTA member country, and (ii) prior to the January 30, 2004 effective date of the Plicchi reference.

4. Evidence of completion of invention of the subject matter claimed in claims 1-16, 18-21, 23, 24, 35-37, 39-42, 44 and 45 prior to the January 30, 2004 effective date of the Plicchi reference is annexed hereto as Exhibits A and B. Specifically, Exhibits A and B evidence an actual reduction to practice of the claimed invention in a WTO member country, prior to the January 30, 2004 effective date of the Plicchi reference.

5. Exhibit A consists of one video clip entitled "Robotic_Steering", recorded on one CD. Exhibit B consists of nine exemplary screen prints from the "Robotic_Steering" video clip of Exhibit A.

6. For example:

(a) Exhibit A at time points 00:00-00:48 and 01:15-02:15, and Exhibit B at Screen Prints 1-3 show a robot for use with a steerable catheter that includes a thumb control adapted to control a deflection of a distal tip of the catheter and a position sensor, fixed in a vicinity of the distal tip of the catheter, and adapted to generate a position signal, the robot comprising: an end-effector, adapted to be coupled to the thumb control; and a controller, adapted to receive the position signal, the position signal being indicative of six dimensions of location and orientation information, the controller being adapted to drive the end-effector to

position the distal tip of the catheter at a desired position based on the six dimensions of location and orientation information by manipulating the thumb control;

(b) Exhibit A at time points 02:45-03:12, and Exhibit B at Screen Prints 4-7 show an apparatus comprising: a steerable catheter, comprising: a distal tip adapted to be controllably deflectable in no more than two directions for any given rotation of the distal tip, such that a set of all points to which the tip can be deflected at the given rotation forms a deflection curve for the given rotation; and a position sensor, fixed in a vicinity of the distal tip, and adapted to generate a position signal indicative of six dimensions of location and orientation information; a robot, adapted to manipulate a proximal end of the catheter; and a control unit, adapted to: receive the position signal, and position the distal tip of the catheter at a target by driving the robot to: position the distal tip of the catheter in a vicinity of the target, responsive to the position signal based on the six dimensions of location and orientation information, rotate the proximal end of the catheter in order to cause the distal tip of the catheter to roll to a rotation the deflection curve of which includes the target, the rotation determined responsive to the position signal, and deflect the distal tip of the catheter along the deflection curve to the target; and

(c) Exhibit A at time points 03:15-03:45 and Exhibit B at Screen Prints 2, 8 and 9 show an apparatus comprising: a steerable catheter having a distal tip, the catheter comprising a position sensor, fixed in a vicinity of the distal tip, and adapted to generate a position signal indicative of six dimensions of location and orientation information; a robot, adapted to be coupled to a proximal end of the catheter; and a control unit, adapted to: drive the robot to apply rotation to the proximal end of the catheter, receive the position signal, responsive to the six dimensions of location and orientation information of the position signal, determine a

roll of the distal tip of the catheter, and responsive to a determination that the roll lags the rotation, drive the robot to move a portion of the proximal end of the catheter.

7. We further declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under 18 U.S.C. §1001 and that such willful false statements may jeopardize the validity of the Application or any patent issued thereon.

Date:

13.03.10

A. Govari
Assaf Govari

Date:

13/3/10

Andres Claudio Altmann
Andres Claudio Altmann

Date:

13/3/10

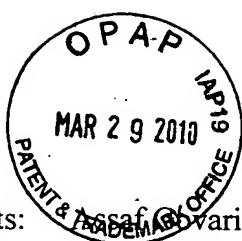
Yaron Ephrath
Yaron Ephrath



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EXHIBIT A

Video clip entitled "Robotic_Steering" recorded on attached CD



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EXHIBIT B

Screen prints of video clip entitled "Robotic_Steering" included in Exhibit A

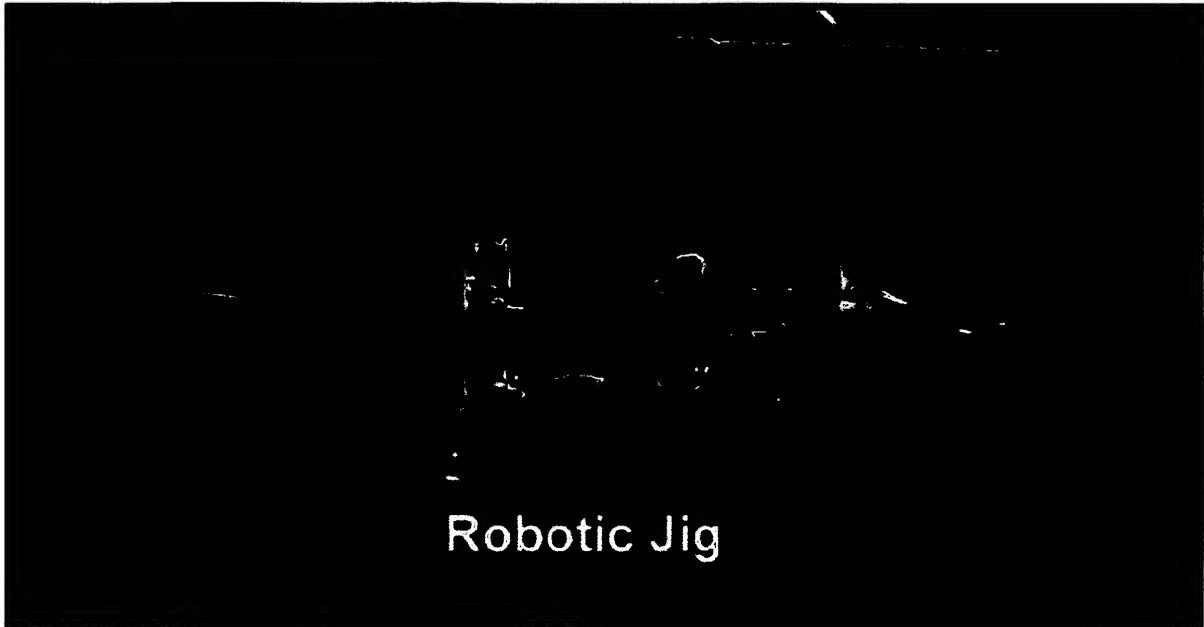
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SCREEN PRINT 1



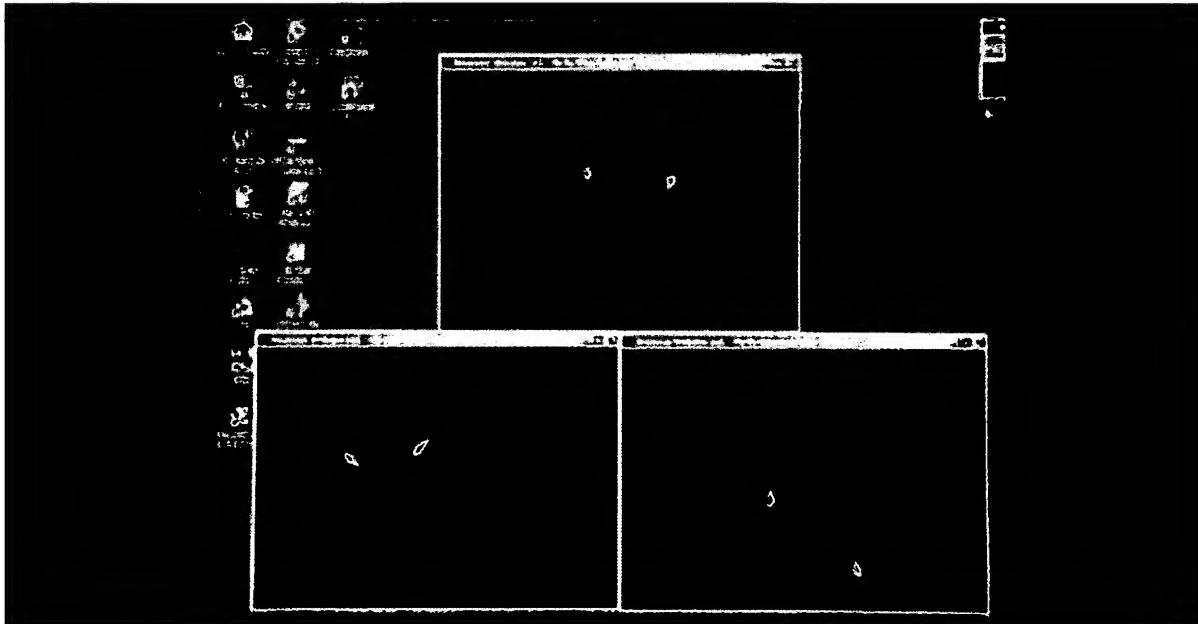
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SCREEN PRINT 2



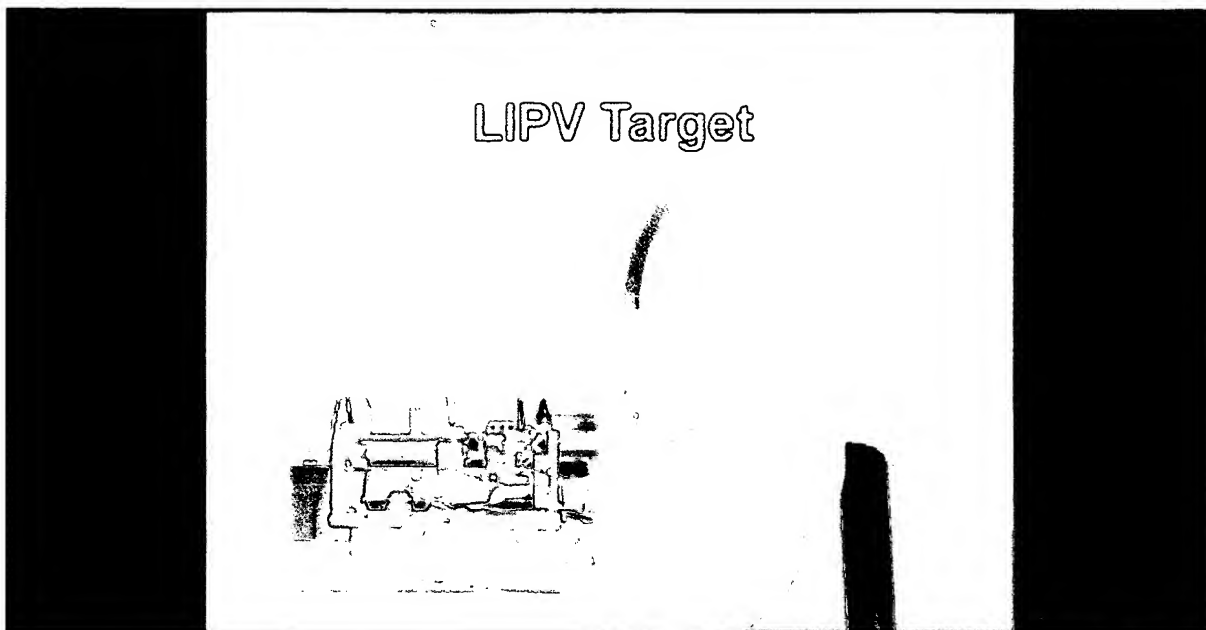
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SCREEN PRINT 3



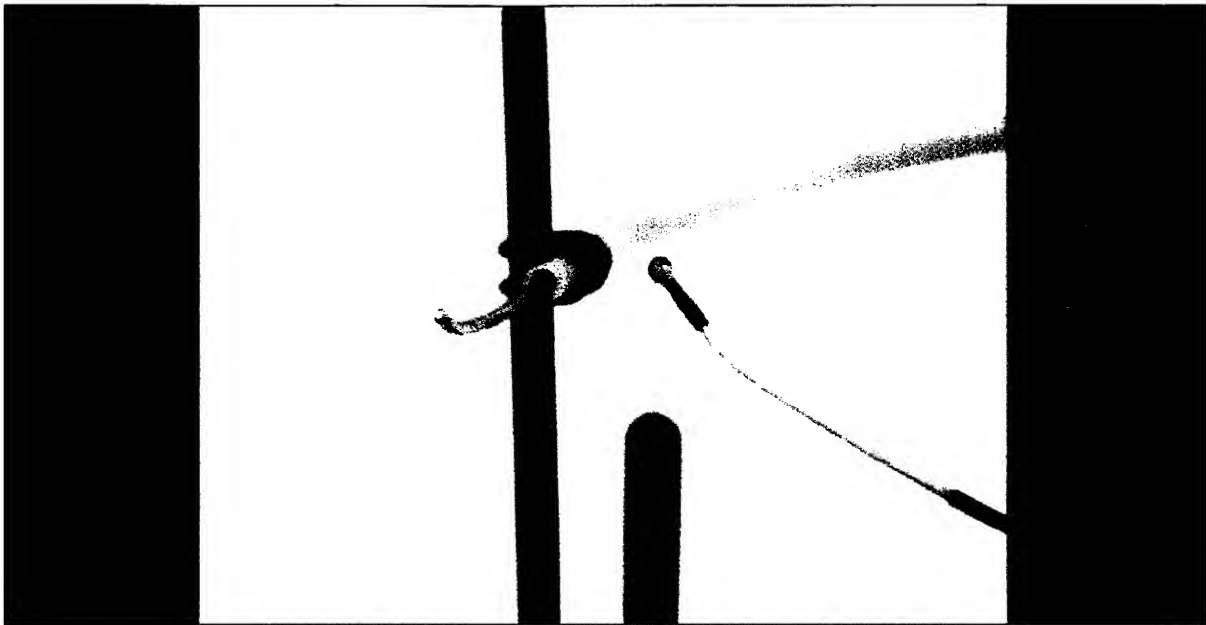
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SCREEN PRINT 4



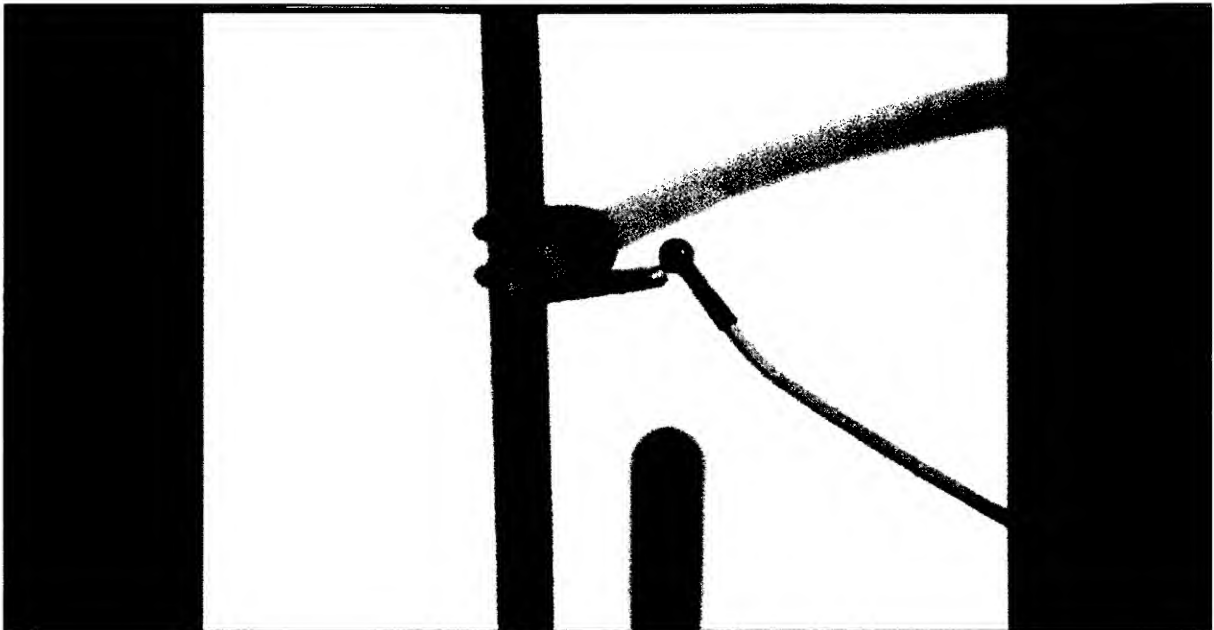
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SCREEN PRINT 5



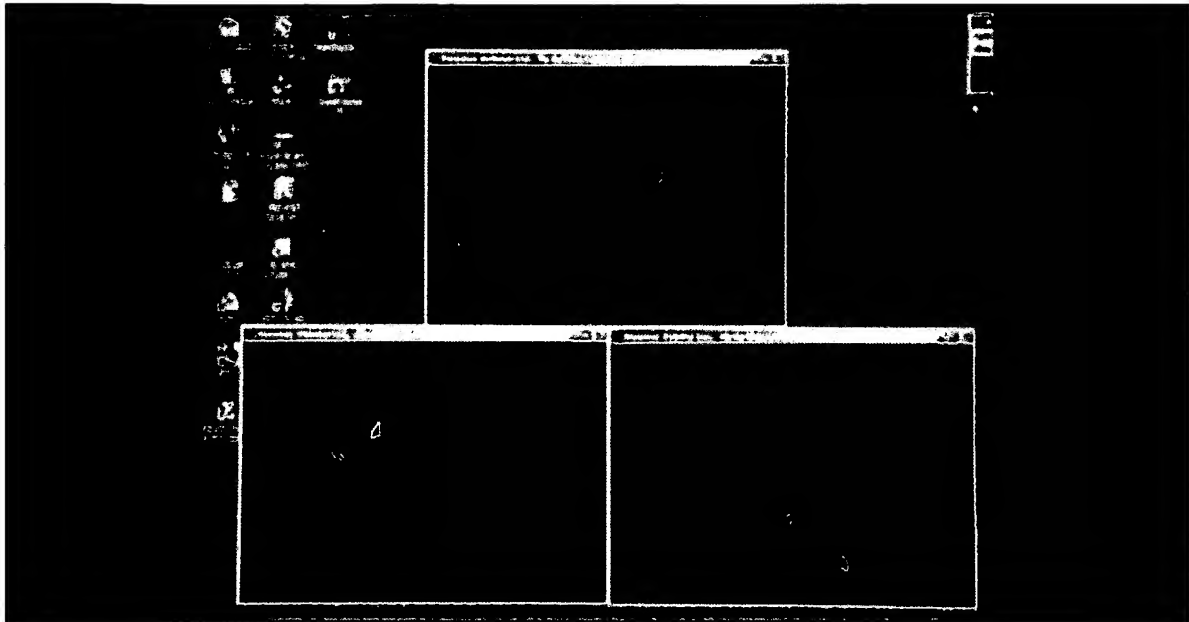
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SCREEN PRINT 6



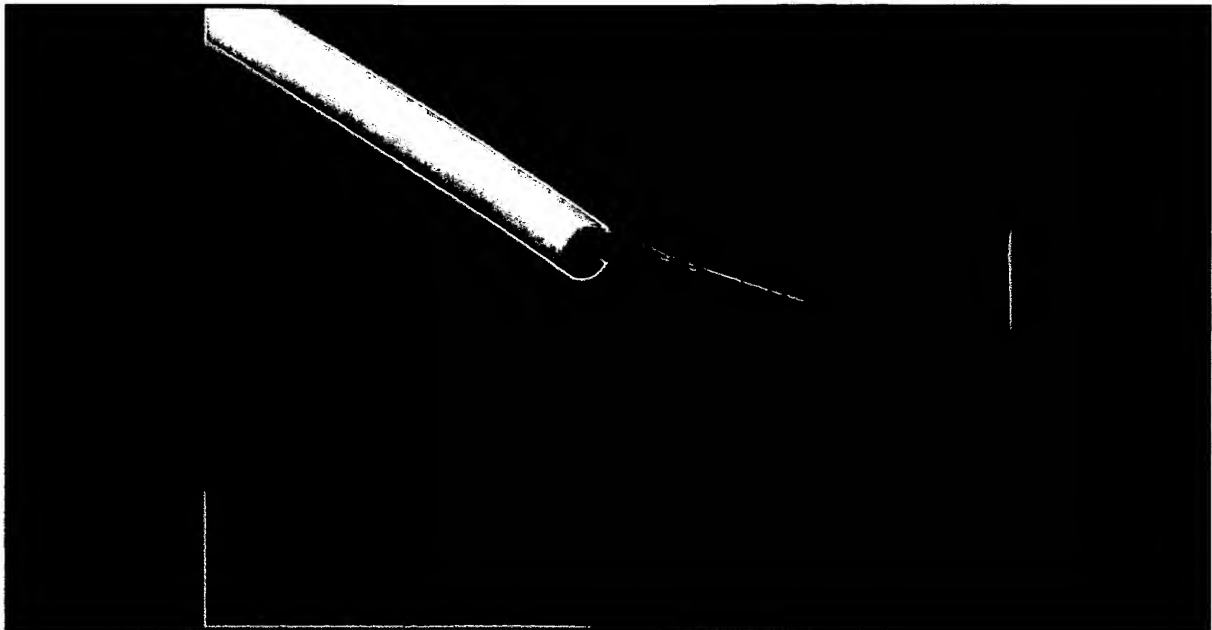
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SCREEN PRINT 7



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SCREEN PRINT 8



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SCREEN PRINT 9

